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510(k) SUMMARY

BÂRRX Medical's HALO^{90} Coagulation System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Phone: (408) 328-7302
Facsimile: (408) 328-7395

Contact Person: Viorica Filimon

Date Prepared: September 11, 2006

Name of device and Name/Address of Sponsor:

HALO^{90} Coagulation System
HALO^{90} Coagulation Catheter
HALO^{90} Coagulation Generator

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Common or Usual Name(s):

Electrosurgical Coagulation System

Classification Name:

Product code: GEI
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories
Device Class: II
Classification panel: General & Plastic Surgery

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Predicate Device(s)

K060169 HALO^{90} Coagulation System-BÂRRX Medical Inc.

Intended Use / Indications for Use

The **HALO^{90}** Coagulation System intended use is for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract.

The **HALO^{90}** Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Technological Characteristics

The **HALO^{90}** Coagulation System consists of the **HALO^{90}** Coagulation Generator with a disposable single-use **HALO^{90}** Coagulation Catheter model 90-9100, output cable, and an optional footswitch. The **HALO^{90}** Coagulation System performance and mode of operation is substantially equivalent to the already cleared **HALO^{90}** Coagulation System (with catheter model 1520F).

Substantial Equivalence

The **HALO^{90}** Coagulation Catheter model 90-9100 and the predicate devices: **HALO^{90}** Coagulation Catheter model 1520F, have the same intended use, indications for use, technological characteristics, and principles of operation. The technological differences between the **HALO^{90}** Coagulation Catheter and the predicate device are: (1) The surface electrode was reduced from 15 x 20 mm to 13 x 20 mm to allow a smaller profile of the distal end; (2) The length of the catheter shaft was increased from 105 cm to 160 cm for ergonomic issues and to allow the use with a wider range of endoscopes; (3) The catheter maximum profile was reduced from 17.5 mm to 13.5 mm. (4) Changes in materials.
All these differences were evaluated on bench and did not raise questions regarding safety and efficacy. Thus the devices are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Viorica Filimon
VP Regulatory/Quality
BÂRRX Medical, Inc.
540 Oakmead Parkway
SUNNYVALE CA 94085

NOV - 9 2006

Re: K062723
Trade/Device Name: BÂRRX HALO^{90} Coagulation Catheter, Model 90-9100
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 14, 2006
Received: October 18, 2006

Dear Ms. Filimon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K062723

Device Name: **HALO**^{90} Coagulation System

Indications for Use:

The **HALO**^{90} Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Prescription Use ✓
(Part 21 C.F.R. 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use____
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device System Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062723

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